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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/121,239	07/23/1998	RICHARD C. HARVEY	GP091-02.UT	3098
21365	7590	12/22/2003		
GEN PROBE INCORPORATED 10210 GENETIC CENTER DRIVE SAN DIEGO, CA 92121			EXAMINER GIBBS, TERRA C	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 12/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/121,239

Applicant(s)

HARVEY ET AL.

Examiner

Terra C. Gibbs

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-10,12,14-18 and 20-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 15-17 is/are rejected.
- 7) ☒ Claim(s) 5-10,12,14,18 and 20-27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

This Office Action is a response to the Amendment filed September 8, 2003 and May 29, 2003.

Claims 1, 3, 5, 9, 18, 20-23, and 26 have been amended. Claim 19 has been canceled. New claim 27 is acknowledged.

Claims 1-3, 5-10, 12, 14-18, and 20-27 are pending in the instant application.

Response to Amendment

The Amendment filed September 8, 2003, is in response to A Notice of Non-responsive Amendment, which was filed on August 8, 2003. After careful consideration it was determine that this notice was issued in error and is hereby withdrawn.

Response to Remarks

The Amendment filed May 29, 2003 is acknowledged. Applicants Amendment to the Specification to include SEQ ID NOs. is acknowledged. Applicants Amendment to the Abstract is acknowledged.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 5-10, 12, 14-18 and 21-26 were rejected under 35 U.S.C. 112, first paragraph as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This rejection is withdrawn** in view of Applicants amendment to the claims to include language provided in the specification.

Claim Rejections - 35 USC § 102

Claims 19 and 20 were rejected under 35 U.S.C. 102(b) as being anticipated by Qiagen Oligotex Direct Protocol for isolation of PolyA+ mRNA from cytoplasm of cultured cells. This rejection is withdrawn in view of Applicants amendment to cancel claim 19 and amend claim 20 to depend from independent claim 6.

It is noted that the previous Office Action indicated claims 1-3, 6-10, 12, 14-18 and 21-26 as free of the prior art since the closes prior art, Sooknanen et al. cited previously taught only the use of *bcr-abl* hybrid primers, and not *abl* or *bcr* specific primers. However, after very careful consideration of the claims, a new grounds of rejections is presented below:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 15, 16, and 17 are rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "at least one nucleic acid polymerase activity". Claims 2, 3, 16, and 17 recite the term "polymerase activity". The term "polymerase activity" comprises an activity and is unclear. Replacement with the language "an enzyme having nucleic acid polymerase activity" as supported on page 10, line 24 of the instant Specification, would overcome the instant rejection.

Claim 15 recites, "one or more oligonucleotides suitable for use in the method of claim 14, have a sequence selected from the group consisting of SEQ ID NO:1 to SEQ ID NO:23, SEQ ID NO:26 and SEQ ID NO: 27." Claim 15 has a grammatical error (see after the number 14) and is unclear. Additionally, claim 15 is also missing a conjunction or noun to connect the second part of the claim (see after the number 14) and is unclear. Claim 15 also improperly recites Markush groups, rendering the claim vague and indefinite, and instead should, in part, recite: "selected from the group consisting of" See MPEP 2173.05(h).

Claim Rejections - 35 USC § 102

Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Kacian et al. [U.S. Patent No. 5,399,491].

Claim 15 recites, "one or more oligonucleotides suitable for use in the method of claim 14, have a sequence selected from the group consisting of SEQ ID NO:1 to SEQ ID NO:23, SEQ ID NO:26 and SEQ ID NO: 27". Have, having, or has is considered to be open language and therefore the language "have a sequence selected from the group consisting of" in claim 15, encompasses one or more oligonucleotides suitable for use in the method of claim 14 comprising a sequence selected from the group consisting of SEQ ID NO:1 to SEQ ID NO:23, SEQ ID

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NO:26 and SEQ ID NO: 27. Since claim 15 is drawn to a composition, the limitation “suitable for use in the method of claim 14” holds no patentable weight since a method of intended use does not change the composition. Kacian et al. disclose AAQ86635, a modified promoter primer for the CML major breakpoint region, with the following sequence:

5'-GACCAACTCGTGTGTGAACTCCA-3' (see Kacian et al., Example 18). AAQ86635 is 100% identical to SEQ ID NO:5 of the instant invention.

Therefore Kacian et al. anticipate claim 15.

Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Hogan et al. [U.S. Patent No. 5,424,413].

Hogan et al. disclose a branched nucleic acid probe with the following sequence:

5'-GACTGTCCACAGCATTCCGCTGACC-3' (see Hogan et al. SEQ ID NO:17). This nucleic acid probe is 100% identical to SEQ ID NO:9 of the instant invention.

Therefore Hogan et al. anticipate claim 15.

Conclusion

Claims 5-10, 12, 14, 18 and 20-27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is (703) 306-3221. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 746-8693.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

tcg
December 12, 2003


KAREN A. LACOURCIERE, PH.D
PRIMARY EXAMINER